

Environmental Management Consolidated Business Center (EMCBC)

Subject: EMCBC Quality Assurance Program (QAP)

Policies, Procedures,	APPROVED:	(Signature on File)	
and Plans		EMCBC Director	_

1.0 PURPOSE

The purpose of this document is to describe the Quality Assurance Program (QAP) as required by DOE O 414.1C for the Department of Energy (DOE) at the Environmental Management Consolidated Business Center (EMCBC) and applicable Service Level Agreement (SLA) sites. This document provides personnel with the information, and references to additional information, needed to implement Quality Assurance (QA) and achieve quality within the EMCBC.

2.0 SCOPE

This document is directed toward the application of the QA criterion to the federal employees' role. Unless specifically noted otherwise, each of the requirements apply to work performed by the federal employees.

3.0 APPLICABILITY

The requirements contained within this document apply to all EMCBC and participating SLA site federal personnel.

4.0 REQUIREMENTS & REFERENCES

4.1 Requirements

- 4.1.1 DOE O 414.1C, Quality Assurance
- 4.1.2 ASME NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications

4.2 References

- 4.2.1 DOE G 414.1-1A, Management Assessment and Independent Assessment Guide
- 4.2.2 DOE G 414.1-2A, Quality Assurance Management System Guide
- 4.2.3 DOE G 414.1-3, Suspect/Counterfeit Items Guide
- 4.2.4 DOE G 414.1-4, Safety Software Guide
- 4.2.5 DOE G 414.1-5, Corrective Action Program Guide

5.0 DEFINITIONS & ACRONYMS – See PD-411-02, Definitions & Acronyms

- 6.0 <u>RESPONSIBILITIES</u> EMCBC or Service Level Agreement Site Senior Official
 - 6.1 Develop and implement an approved QAP governing the work under their purview, including software development/use, in accordance with requirements defined in DOE O 414.1C, *Quality Assurance*, Suspect/Counterfeit Items prevention requirements (DOE O 414.1C, Attachment 3), Corrective Action Management Program requirements (DOE O 414.1C, Attachment 4), and Safety Software Quality requirements (DOE O 414.1C, Attachment 5). Identify the senior management position assigned this responsibility.
 - 6.2 Submit their QAP to the appropriate Secretarial Official for review, resolution of differences of opinion, and approval.
 - 6.3 Review and, where delegated authority to do so, approve new and revised QAPs for contractors within their purview.
 - NOTE: The scope and rigor of review must be graded based on the status of the contractor's prior quality performance (e.g., past regulatory/contract noncompliance, performance metrics, or any third-party QAP certification). QAPs must be reviewed and approved or rejected within 90 calendar days of receipt.
 - 6.4 Perform independent assessments of contractor organizations to evaluate the adequacy and QAP implementation effectiveness.
 - NOTE: The frequency and scope of assessments must be graded based on the status of prior quality performance and any third-party QAP certification. Other suitable methods may be used in combination with independent assessments.
 - 6.5 Periodically report management assessment results to their organization's Secretarial Official describing the effectiveness of field element and contractor QA implementation.
 - 6.6 Prepare and implement a Corrective Action Plan (CAP) to address all findings in Corrective Action Management Program (DOE O 414.1C, Attachment 4) assessment reports, and enter, track, and report the status of the CAP in the Corrective Action Tracking System (CATS).
 - 6.7 Complete the CAP and conduct follow-up review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings. Approve the effectiveness review report and follow-up report recommendations.

7.0 GENERAL INFORMATION

The U.S. Department of Energy (DOE) Order, <u>DOE O 414.1C</u>, <u>Quality Assurance</u>, is applicable to all Environmental Management Consolidated Business Center (EMCBC) and Service Level Agreement (SLA) site federal personnel. This Quality Assurance Program (QAP) describes the method by which Quality Assurance (QA) will be

implemented and quality achieved within the EMCBC. This QAP has been written in a manner that will allow for those sites that are serviced by the EMCBC (i.e., those sites with a SLA) to also adopt this QAP. Therefore, reference to federal employees in the remainder of this QAP will include both EMCBC and participating SLA site federal employees.

This QAP presents each of the DOE O 414.1C 10 QA criteria followed by General Information including management expectations and a discussion that amplifies the expectations and provides necessary background. (Suspect/Counterfeit Items Prevention, Corrective Action Management Program, and Safety Software Quality Requirements from DOE O 414.1C, Attachments 3, 4, and 5, are addressed in Attachments A, B, and C of this QAP, respectively.) This information is directed toward the application of the criterion to the federal employees' role. Unless specifically noted otherwise, each of the requirements listed will apply to work performed by the federal employees. This document, under a heading of Implementation, provides a reference to EMCBC procedures and documents that implement the applicable requirements. If a SLA site chooses to utilize this QAP, then their supplemental Quality Assurance Implementation Plan (QIP) will identify all applicable procedures and documents for implementation of their QA program. The QIP is developed utilizing the sample EMCBC QIP as a template (see Attachment G, Quality Assurance Implementation Plan). The specific SLA site performs a gap analysis to determine the necessary procedures and documents for their site QA program needs. This is included within their QIP with reference to EMCBC procedures as needed. Two of the criteria, Design requirements and Inspection and Acceptance Testing requirements, generally do not apply to the work performed by federal employees, and are addressed accordingly in this QAP. The DOE O 414.1C QA requirements are applied to DOE work performed by contractors and subcontractors through regulation (10 CFR 830 Subpart A) and/or contract (DOE O 414.1C, Attachment 2, Contractor Requirements Document). DOE management retains the overall oversight responsibility for these and other areas where DOE work is performed by contractors or subcontractors.

QA is defined as those actions that provide confidence that quality is achieved. QA is the responsibility of each federal employee. Specifically, the responsibility for QA resides with those individuals performing tasks, as well as those checking or verifying a task is properly performed. However, the Senior DOE Official retains the overall responsibility and accountability for the scope and implementation of their QA Program. The Senior DOE Official for the EMCBC (in this case, the EMCBC Director) has delegated the responsibility for development and implementation of the QAP and the applicable EMCBC QIP to the EMCBC Assistant Director, Office of Logistics Management. In the case of SLA sites, the delegation flows from the Senior DOE Official to their designated Point-of-Contact (POC) regarding development and implementation of the applicable SLA site QIP. Under this arrangement, the EMCBC retains responsibility for the development and maintenance of the QAP. The level of control and verification appropriate for a task is dependent upon the consequences of the task not being performed properly. This is defined as applying quality assurance using a graded approach (see Attachment D, *Graded Approach*).

Federal employees typically perform two functions: (1) performing work that is inherently a government responsibility and, (2) managing contracts (including contractor oversight) where the primary responsibility for achieving quality results resides with the contractor. The overall role of the federal employee includes the following:

- Understanding and helping to shape the expectations of customers (DOE-Headquarters, stakeholders, regulators, contractors, and those internal to either the EMCBC or SLA site).
- Defining and prioritizing the work of SLA project contractors, including setting aggressive, but realistic performance expectations.
- Establishing the right contracts and requirements to complete the work.
- Requesting adequate funding to meet DOE obligations.
- Authorizing work and providing government-furnished items and services necessary to complete the work.
- Maintaining an honest and accurate view of the current state of affairs, through monitoring, assessments, knowledge, analysis, and open communication using an assortment of channels.
- Obtaining and maintaining required training and certifications.
- Ensuring the government receives value for work performed, consistent with its cost.
- Ensuring corrective actions and improvement actions resulting from assessments are, in fact, effective and the feedback and lessons learned are captured and result in continuous improvement for EMCBC and SLA site personnel and contractors.

When employees comply with the processes, procedures, and other documents identified herein, they are implementing the EMCBC QAP. This QAP, along with the many referenced procedures, has included the principles of DOE Integrated Safety Management. The EMCBC and applicable SLA sites Integrated Safety Management System (ISMS) and the QAP are fully integrated as required by the governing requirements (see Attachment F, *Integrated Management System*).

8.0 PLAN

The following sections describe the implementation of the 10 QA Criteria from DOE O 414.1C, *Quality Assurance*.

8.1 PROGRAM

The following are the **Management/Criterion 1 - Program** requirements from DOE O 414.1C:

- (a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
- (b) Establish management processes, including planning, scheduling, and providing resources for work.

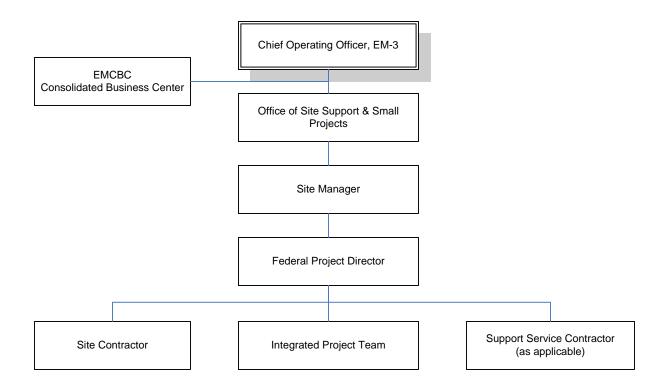
8.1.1 GENERAL INFORMATION

Management Expectations:

- All federal employees shall be familiar with and facilitate achievement of the management expectations included in this document.
- DOE management shall establish and implement Work Plans for EMCBC or SLA site mission-related activities in a controlled manner.
- This QAP shall be maintained current.
- The QAP will meet requirements consistent with guidance provided in <u>DOE G 414.1-2A</u>, *Quality Assurance Management System Guide*.

The voluntary national consensus standard, ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, is applicable in the implementation of this QAP (see Attachment D, *Graded Approach*, and Attachment E, *Application of ASME NQA-1*). The QAP is implemented by: (1) incorporating the commitments of this document into EMCBC and SLA project procedures, processes and plans, and (2) employees following these procedures when they perform work. A graded approach based on the relative importance of the activity to safety, safeguards and security, and other pertinent areas of management consideration, including the application of voluntary consensus standards, is used in applying the requirements of this document as described in Attachment D and Attachment E.

Line management for execution of the work extends from Environmental Management (EM) Headquarters (HQ), EM-3, to EM-HQ Office of the Site Support and Small Projects, to the Site Manager and Federal Project Director (FPD), and to managers whose companies have contracts directly with the DOE (contractors).



The line management organizational structure is as follows:

Where necessary, SLA projects coordinate and integrate activities with the EMCBC. Lines of communication, feedback mechanisms, and interfaces with stakeholders, regulators, HQ, and support organizations are established. The Senior DOE Official ensures that planning, scheduling, providing resources, and the graded approach are utilized to accomplish federal employee completion of work. The Functions, Responsibilities and Authorities Manual (FRAM) is another tool utilized to ensure all requirements have been identified and associated responsibilities have been assigned. The Quality Assurance Implementation Plan defines these linkages to each QA criterion (see Attachment G, *Quality Assurance Implementation Plan*).

8.1.2 IMPLEMENTATION

- (a) This document describes the EMCBC Quality Assurance Program. In addition, this QAP has been developed in a manner that will allow any of the EMCBC SLA sites to easily adopt it for their activities. The QAP complies with <u>DOE 414.1C</u>, *Quality Assurance*.
- (b) An approved organizational chart, which can be found at either the EMCBC web site or the applicable SLA QIP, reflects the organizational structure, interfaces, and levels of authority in the organization.
- (c) A FRAM is provided to ensure all requirements and functional responsibilities are identified and assigned.

(d) The Senior DOE Site Official, as identified in the respective organizational chart, is responsible to assure adequate planning, scheduling, and resources are provided to implement the QAP.

Implementing Procedures and Documents:

- EMCBC Organization Chart
- EMCBC Strategic Plan
- IP-111-01, Mission and Function Statement for the EMCBC
- PD-411-01, EMCBC FRAM
- PD-411-02, Definitions & Acronyms
- PL-414-01, EMCBC Quality Assurance Program

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

8.2 PERSONNEL TRAINING AND QUALIFICATION

The following are the **Management/Criterion 2 – Personnel Training and Oualification** requirements from DOE 414.1C:

- (a) Train and qualify personnel to be capable of performing assigned work.
- (b) Provide continuing training to personnel to maintain job proficiency.

8.2.1 GENERAL INFORMATION

Management Expectations:

Individual Development Plans (IDPs) are developed and maintained by employees.

The success of any organization requires members of the organization to be competent in the work they perform. Training is provided to employees to maintain or improve job performance, enhance existing skills, and develop new skills. Managers are responsible for ensuring personnel are fully qualified for their positions. The Office of Human Resources staff members are responsible for reviewing applicant qualifications necessary to perform satisfactorily in a federal position and ensuring that only qualified personnel are referred for consideration. DOE or DOE-contracted vendor provided training identified by the supervisor is made available, if necessary, to improve knowledge or skills specific to the job and/or organization.

Training includes formal and informal training, education, developmental, and other learning assignments; application of acquired knowledge, skills, and experience to workplace responsibilities; and use as a tool to recruit and maintain a talented, diverse, and versatile workforce. Methods of training include reading assignments, observation and performance of activities, feedback from co-workers and managers, briefings, and formal training classes, among others. The extent of training is commensurate with the scope, complexity, and nature of the respective task. Education, experience, and formal training comprise the basis for qualification.

Employee-specific training needs are documented in an Individual Development Plan, which is usually developed/updated annually in conjunction with the annual performance planning process. IDPs provide the structure for an effective training and development program and provide activities that are carried out in an organized, systematic manner, with established goals clearly defined and sequenced. IDPs are designed for initial training and qualification, as well as maintenance of proficiency and progressive improvement. IDPs are designed to stimulate professional development and may include managerial, communication, and interpersonal skills. Additional training specified in the IDP maintains and promotes improvement in the incumbent's job performance, or prepares personnel for new responsibilities.

Qualifications for specific job categories are based on requirements established by the U.S. Office of Personnel Management (OPM), DOE Directives, other requirement documents, or management. Management reviews their positions to determine:

- If critical and unique job functions or tasks require highly technical, specialized skills;
- Whether competency must be demonstrated before performance (i.e., OPM minimum qualification requirements) or within a specified timeframe after entering the position (e.g., Technical Qualification Program (TQP) qualification within 18 months of entering the position);
- Whether a specialized certification may be required.

Based on the review, qualification requirements that provide evidence of employee proficiency through a practical and/or written examination process may be established. The DOE directives related to this criterion are DOE O 360.1B, Federal Employee Training, DOE M 360.1-1B, Federal Employee Training Manual, DOE M 426.1-1A, Federal Employee Training Manual, DOE M 426.1-1A, Federal Technical Capability Manual, Training Manual, Traini

8.2.2 IMPLEMENTATION

(a) The method and process for ensuring personnel are trained and qualified and capable of performing their assigned work is identified in <u>IP-361-01</u>, <u>Training and Qualification for Federal Employees</u> or as described in the applicable SLA Site Quality Assurance Implementation Plan.

PL-414-01, Rev. 1

(b) Specific training includes General Employee Training, Job-Specific Training, Assessment and Oversight Training, Lead Auditor Training, Technical Qualification Training (including Safety Software Quality Assurance per Attachment C, Safety Software Quality Requirements), and Professional Qualification/Certification Training as applicable.

8.3 **QUALITY IMPROVEMENT**

The following are the **Management/Criterion 3 – Quality Improvement** requirements from DOE 414.1C:

- (a) Establish and implement processes to detect and prevent quality problems.
- (b) Identify, control, and correct items, services, and processes that do not meet established requirements.
- (c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
- (d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

8.3.1 GENERAL INFORMATION

Management Expectations:

- Management shall set performance goals and standards.
- Management shall establish metrics that measure performance.
- Nonconforming items, services and processes will be identified, segregated, and dispositioned before use.
- Corrective action plans shall be developed for findings, approved by the assessing organization, and implemented according to the plan.
- Completed corrective actions shall be verified by the assessing organization.

In order for quality improvement to occur, it is necessary to have systems that identify problems. Problem identification can occur as a result of self-assessments, independent or external assessments, anomalous behavior of some measured quantity against a predefined metric, benchmarking, failure to achieve performance goals or accomplish improvement plans, or as a result of the occurrence of an event. Problem identification can also result from unfulfilled expectations of customers served by the organization. In most cases, problems are associated with deviations or inconsistencies with a requirement, or failures to meet customer, or management expectation. Items, services, or processes that conform to requirements and meet known customer or management expectation but still need improvement generally require such improvement because the activity could have been performed more effectively or efficiently.

Problems with potential programmatic or safety significance or that is widespread, continuing, multiple, or repetitive in nature should be afforded special attention. Problems must be entered into a corrective action database and identified to management for proper attention.

Responses to findings identified during HQ Independent Oversight; Environment, Safety, and Health evaluations; Security or Cyber Security evaluations; and Emergency Management assessments, Judgments of Need for Type A accident investigations, and for other sources as directed by the Secretary or Deputy Secretary are subject to the requirements identified in Attachment B, *Corrective Action Management Program*. This includes requirements to prepare a comprehensive Corrective Action Plan (CAP) and to track and report CAP data to Headquarters.

The EMCBC Issues/Action Management System requires that the receiving organization (e.g., the SLA site Senior DOE Official) designate a Point-of-Contact (POC) for items subject to Attachment B. The POC is required to manage the process in strict compliance with the requirements identified in Attachment B. The designated POC is responsible for coordinating responses, transmitting the CAP, and preparing closeout documentation in accordance with the requirements.

Corrective action should include an analysis of causal factors. Formal root cause analysis should be considered based on the complexity of the identified issue. Root causes should be identified and documented using an authoritative methodology for root cause identification, such as DOE G 231.1-2, Occurrence Reporting Causal Analysis Guide.

Quality Improvement requirements are further defined in the EMCBC Oversight Plan and associated procedures. The EMCBC Issues/Action Management System contributes to providing accurate technical, business, and operational performance information to management and staff. Improvement processes maintained by this management system include, Self-Assessment, Independent Oversight, Lessons Learned, and Performance Metrics.

8.3.2 IMPLEMENTATION

Processes to detect, communicate, and prevent quality problems can be associated with operational awareness activities such as: facility tours/walk-throughs, work observation, document reviews, meeting attendance and participation, and ongoing interactions with contractor workers, support staff, and management.

Other processes include assessments of facilities, operations, and programs; assessments of contractor assurance systems; evaluations of contractor performance; and self-assessment of DOE line management functions and performance.

Implementing Procedures and Documents:

- PL-226-01, EMCBC Oversight Plan
- IP-414-02, Assessment Procedure for Federal Employees
- IP-414-03, EMCBC Issues/Action Management System
- IP-230-01, Operating Experience/Lessons Learned

PL-414-01, Rev. 1

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

8.4 DOCUMENTS AND RECORDS

The following are the **Management/Criterion 4 – Documents and Records** requirements from DOE 414.1C:

- (a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
- (b) Specify, prepare, review, approve, and maintain records.

8.4.1 GENERAL INFORMATION

Management Expectations:

- New or revised requirements shall be analyzed to determine impact on implementing procedures and/or contracts.
- Policies, procedures and plans shall be deployed in a manner that makes the documents readily available to the users.
- Procedures shall identify records that need to be created and maintained.
- Records shall be maintained until they are transferred to permanent storage.
- Records shall be transferred to permanent storage in a timely manner when they are no longer needed by the organization.

Documents

Documents establish requirements or define how work is to be performed. EMCBC or SLA site documents that establish policy, prescribe work, or specify requirements are required to be prepared, reviewed, approved, issued, used, and revised in a controlled manner using appropriate technical and quality standards. Requirements typically originate from laws, regulations, and/or DOE Directives. New or revised requirements documents are analyzed to determine impact on implementing documents and/or contracts.

Documents that are to be controlled by EMCBC and SLA projects include those identified in the applicable QIP.

Records

In general terms, a record is recorded information, in any format, that is created in the course of business, received for action, or needed to document DOE activities. Records are typically the outcome of implementing documents and reflect what was done. The legal definition of a record includes ... all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government under Federal law or in connection with the transaction of public business and preserved or

appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them. (44 United States Code 3301) Project personnel performing work prepare, collect, protect, and retain records in a manner that makes the record retrievable, useable, and auditable. Written procedures govern records required to support ongoing activities (active records) as well as records transferred to records retention areas (inactive records). Records must accurately reflect the work performed, be legible and traceable to the applicable work and the responsible personnel.

Completed records are maintained in active files until they are no longer required to support ongoing activities or have met legal retention requirements. While in the custody of the responsible personnel, these records are protected from loss or damage by employing filing equipment suitable for the level of protection required as defined in records management regulations. When records are no longer required to support ongoing activities, the responsible personnel transfer them from active files to long-term, secured storage of the records or as determined by legal requirements. The records management program addresses the lifecycle of records, which is the period of time that records are in the custody of Federal agencies. The lifecycle consists of three stages: creation or receipt; maintenance or use; and disposition.

8.4.2 IMPLEMENTATION

Implementing Procedures and Documents:

Documents

• <u>IP-250-01</u>, <u>Preparation</u>, <u>Review</u>, <u>Approval</u>, <u>Revision</u>, <u>and Distribution of EMCBC</u> Implementing Procedures, Policy Statements, and Program Descriptions

Records

- PS-243-01, Records Management Policy
- IP-243-02, Vital Records Identification and Protection
- IP-243-03, Identifying, Filing & Maintaining Records
- IP-243-04, File Plan Creation and Maintenance
- PL-243-05, EMCBC Records Disaster, Prevention, Mitigation, and Recovery Plan
- IP-243-06, Electronic Records Management
- IP-243-07, Disposition of Records

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

8.5 WORK PROCESSES

The following are the **Performance/Criterion 5 – Work Processes** requirements from DOE 414.1C:

- (a) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
- (b) Identity and control items to ensure their proper use.
- (c) Maintain items to prevent their damage, loss, or deterioration.
- (d) Calibrate and maintain equipment used for process monitoring or data collection.

8.5.1 GENERAL INFORMATION

Management Expectations:

- Management processes that are routinely performed shall be incorporated in the EMCBC or SLA site QIP.
- EMCBC or SLA documents shall clearly establish the roles and responsibilities for federal employees.
- Federal employees shall follow approved processes when performing assigned tasks.
- Federal employees shall identify and assist in making changes that improve project documents.
- Computer software used by project contractors in nuclear safety related applications shall be verified and validated.

Work performed by federal employees focuses on facilitating contractor work to complete the EM project mission through effective contract management. Procedures describe how federal work will be accomplished. The EMCBC or SLA site QIP is comprised of a set of requirements-based processes, procedures, and program descriptions used by the federal staff to perform their assigned work activities.

EMCBC and SLA sites recognize safety software must have acceptance and operational testing performed prior to use, even if it is off-the-shelf. It is anticipated that only the Prime contractors may possibly purchase or develop safety software. However, if the project office should directly purchase or develop safety software, this must be coordinated with the EMCBC Software Quality Assurance SME to ensure adequate implementation in accordance with the requirements identified in Attachment C, *Safety Software Quality Requirements*.

DOE management delegates implementation authority for (b), (c), and (d) under Criterion 5 through contracts and/or technical direction. DOE management monitors these practices to assure proper implementation through oversight activities.

8.5.2 IMPLEMENTATION

Implementing Procedures and Documents:

• <u>IP-250-01, Preparation, Review, Approval, Revision, and Distribution of EMCBC</u> Implementing Procedures, Policy Statements, and Program Descriptions

8.6 **DESIGN**

The following are the **Performance/Criterion 6 – Design** requirements from DOE 414.1C:

- (a) Design items and processes using sound engineering/scientific principles and appropriate standards.
- (b) Incorporate applicable requirements and design bases in design work and design changes.
- (c) Identify and control design interfaces.
- (d) Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
- (e) Verify/validate work before approval and implementation of the design.

8.6.1 GENERAL INFORMATION

Management Expectations:

- Applying sound engineering and design principles and standards.
- Incorporating applicable design bases.
- Identifying and controlling design interfaces.
- Implementing independent design reviews.
- Verifying design work before approval and implementation.

8.6.2 IMPLEMENTATION

DOE management delegates implementation authority for design through contracts and/or technical direction. DOE management monitors contracted design practices to assure proper implementation through oversight activities.

EMCBC or applicable SLA sites utilize <u>PL-226-01</u>, <u>EMCBC Oversight Plan</u> and <u>IP-414-02</u>, <u>Assessment Procedure for Federal Employees</u> (or other methods as described in the applicable SLA Site Quality Assurance Implementation Plan), written in accordance with DOE O 226.1A, to oversee these activities.

8.7 PROCUREMENT

The following are the **Performance/Criterion 7– Procurement** requirements from DOE 414.1C:

- (a) Procure items and services that meet established requirements and perform as specified.
- (b) Evaluate and select prospective suppliers on the basis of specified criteria.
- (c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

8.7.1 GENERAL INFORMATION

Management Expectations:

- Develop and maintain an integrated acquisition strategy to ensure work is accomplished in compliance with all applicable Laws, Acquisition Regulations, and DOE Orders.
- Mission element oversight shall focus on verifying the contractor is performing work at a cost that provides reasonable value to the Government and that contract terms and conditions are satisfactorily accomplished.
- Government Furnished Services/Items (GFS/I) shall be provided according to contract provisions.

The procurement process is defined by the DOE Office of Procurement and Assistance Management through implementation of applicable Laws and Regulations. Processes include: Acquisition Planning and Management; Contract Management; and Oversight of Contractors.

Procurement functions are predominantly related to contract award and administration of contracts for a variety of goods and services (Suspect/Counterfeit Items Prevention requirements from DOE O 414.1C, Attachments 3, are addressed in Attachment A of this QAP).

The procurement process begins with project staff determining the scope of work to be performed, how the work is to be "packaged" (i.e., one contract or multiple contracts and the type of contract that is most beneficial to the government), duration of the contract, special requirements unique to the scope of work, etc. EMCBC or SLA sites may place and administer a variety of procurement vehicles, e.g., contracts for the clean-up work, interagency agreements for services furnished by other government organizations (e.g., Corps of Engineers), and specialty service contracts. The procurement process includes the following:

- Developing program and acquisition strategies and plans;
- Establishing requirements;
- Selecting qualified contractors;
- Providing direction to the contractor;
- Reviewing and approving of deliverables;
- Evaluating work performed to ensure it meets contract requirements;
- Performing oversight to ensure work is completed in a cost effective, safe, and quality manner; and,
- Furnishing GFS/I in a timely manner.

Because of the lead-time required to place a contract, acquisition planning must be performed sufficiently early. Acquisition strategies are developed bringing together procurement specialists and site management. When QA plans or program documents are required as part of an offeror's response to procurement documents, they are reviewed by qualified personnel during the evaluation process.

Contractor performance is monitored on an ongoing basis. Project monitoring includes facility walkthroughs, observations of contractor activities, reviewing contractor work products or reports, and formal assessments/surveillances that are planned, performed, and documented, with corrective actions verified. Projects may vary their level of oversight depending on: (1) relative importance of the work to the site mission, (2) past performance of contractor, and (3) relative risk of future work. Project mission element monitoring is focused primarily on verification of costs, work progress, implementation of environmental agreements and permits, verifying quality, and verifying/evaluating completion of work in accordance with applicable contract requirements.

Special oversight activities are performed as needed to respond to circumstances that cannot be foreseen; e.g., events/incidents, employee concerns, degrading performance, etc. Monitoring is also conducted to verify the contractor's integrated safety management system is effective. Projects review performance data and other relevant information quarterly and provide timely GFS/I.

As part of the project controls policy, project staff is responsible for verifying work units the contractor claims to have completed are actually completed satisfactorily in accordance with contract provisions. A conditional payment of fee (CPOF) clause allows the government to withhold fee, if the contractor does not perform in accordance with certain contractual requirements or these requirements are disregarded. (The contractual requirements exposed to action under the CPOF clause vary from contract to contract.) Contractor performance against CPOF criteria is evaluated at least annually with the Senior DOE Site Official making the final decision as to the amount of fee, if any, to withhold, where applicable.

The Federal Acquisition Regulations (FAR), Department of Energy Acquisition Regulations (DEAR), and DOE Acquisition Letters are the primary requirements with which EMCBC and SLA projects must comply in the planning, preparation, selection, and award of contracts. Most of the DOE Directives are applicable to some aspect of the overall procurement process, but the directives particularly or uniquely applicable to procurement are, DOE O 540.1A, *Departmental Business Instrument Numbering System*, DOE O 541.1B, *Appointment of Contracting Officers and Contracting Officer Representatives*, DOE O 542.2A, *Unsolicited Proposals*, and the 480 series, which deal with work for others, reimbursable work, technology partnering programs, and cooperative research and development agreements.

As a part of the acquisition process, FAR Part 10 requires market research to be conducted that, among other things, identifies the capabilities of prospective suppliers for meeting the requirements of the agency. In addition, as a part of the acquisition process, past performance of offerors is evaluated. In particular, FAR 15.304 requires: the quality of the product or service shall be addressed in every source selection through consideration of one or more non-cost evaluation factors such as past performance... This part goes on to require: ...past performance shall be evaluated in all source selections for negotiated competitive acquisitions expected to exceed \$1,000,000.

8.7.2 IMPLEMENTATION

The method and processes for ensuring services meet established requirements and performance expectations are evaluated using the following processes:

 Acquisition Planning, Vendor Surveys, Bid Evaluations, Contractor Oversight, Contract Administration, Source Evaluation, etc.

The following procedures and documents need to be followed:

- Procurement policy implementing procedures developed by the DOE Office of Contracting are identified for application by EMCBC Office of Contracting.
- IP-540-01, Procurement Authorities, Delegations, and Responsibilities

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

8.8 INSPECTION AND ACCEPTANCE TESTING

The following are the **Performance/Criterion 8– Inspection and Acceptance Testing** requirements from DOE 414.1C:

- (a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.
- (b) Calibrate and maintain equipment used for inspections and tests.

8.8.1 GENERAL INFORMATION

Management Expectations:

The contractor will conduct inspections and tests to verify that the physical and functional aspects of items, services, and processes meet requirements and that all systems and components are fit for use and acceptance.

This criterion is not applicable to the EMCBC and SLA projects since federal employees do not perform inspection and testing functions. Oversight of the contractor's program to ensure acceptability of work or items includes:

- Inspection/test planning
- Inspection/test methods
- Determining personnel qualifications
- Acceptance criteria
- Calibration of testing equipment
- Documentation

8.8.2 IMPLEMENTATION

DOE management delegates implementation authority for inspection and acceptance testing through contracts and/or technical direction. DOE management monitors inspection and acceptance testing practices through oversight activities.

EMCBC or SLA sites utilize <u>PL-226-01</u>, <u>EMCBC Oversight Plan</u> and <u>IP-414-02</u>, <u>Assessment Procedure for Federal Employees</u> (or other methods as described in the applicable SLA Site Quality Assurance Implementation Plan), developed in accordance with DOE O 226.1A, to ensure contractors are performing inspections and acceptance testing in accordance with requirements.

8.9 MANAGEMENT ASSESSMENT

The following are the **Assessment/Criterion 9– Management Assessment** requirements from DOE 414.1C:

Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

8.9.1 GENERAL INFORMATION

Management Expectations:

- Management assessments shall be one of the means for identifying areas needing correction and/or improvement.
- Results of management assessments shall be documented and deficiencies identified, and tracked, with corrective actions taken.
- Management assessments will meet requirements consistent with guidance provided in <u>DOE G 414.1-1A</u>, <u>Management Assessment and Independent Assessment Guide</u>.

Management assessment is a method used to achieve continuous improvement and/or to identify barriers that hinder improved performance. Managers must periodically evaluate the performance of their organizations in comparison with their mission, responsibilities, and priorities. Management assessments include verifying that roles and responsibilities are known and understood, processes and procedures are effective, appropriate measurement systems are in place and functional, evidence of continuous improvement is readily available, procedures are being complied with, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied. The assessments include evaluating available quality performance data such as the results of independent or external assessments and data from issue tracking and corrective action systems. Areas that present the greatest consequences of failure and the greatest benefit from improvements, if implemented, should receive particular emphasis.

Management assessments include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals. Therefore, significant personal participation by the manager in the assessment is an essential element. Management assessments also identify opportunities for improving cost, schedule, and/or quality of performance. Assessment results shall be documented. Assessments requiring corrective actions shall be tracked per the EMCBC corrective actions process until corrective actions have been completed and verified.

The management assessment process is further defined in the EMCBC Oversight Plan. The implementation of the management assessment process is defined in the EMCBC assessment procedure. The oversight plan and associated assessment procedure includes requirements to:

- Document improvement actions,
- Process lessons learned, as applicable, according to the process,
- Provide a copy of the final self-assessment report so that follow-up improvement actions resulting from the self-assessment can be entered into the issues tracking system for tracking and a record of the assessment can be established in the database.

8.9.2 IMPLEMENTATION

Managers must assess the management processes in accordance with:

■ IP-414-02, Assessment Procedure for Federal Employees

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

8.10 INDEPENDENT ASSESSMENT

The following are the **Assessment/Criterion 10– Independent Assessment** requirements from DOE 414.1C:

- (a) Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement.
- (b) Establish sufficient authority and freedom from line management for independent assessment teams.
- (c) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

8.10.1 GENERAL INFORMATION

Management Expectations:

- Results of independent assessments shall be documented; deficiencies tracked, corrective action plans reviewed and corrective actions verified.
- Independent assessments will meet requirements consistent with guidance provided in DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide*.

In the course of issue identification, proposed solutions or alternative courses of action are brought forward with the objective of seeking to improve organizational excellence. Findings, observations and recommendations are presented in assessment reports that are transmitted formally.

Follow-up of corrective actions is conducted to ensure root causes leading to deficiencies have been identified, generic implications have been addressed, and programs have been appropriately strengthened to prevent recurrence of the deficiencies.

8.10.2 IMPLEMENTATION

Managers must schedule, plan, and conduct independent assessments in accordance with:

■ IP-414-02, Assessment Procedure for Federal Employees

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

- 9.0 <u>RECORDS MAINTENANCE</u> Not Applicable
- 10.0 <u>FORMS USED</u> Not Applicable

11.0 <u>ATTACHMENTS</u>

- 11.1 Attachment A Suspect/Counterfeit Items Prevention
- 11.2 Attachment B Corrective Action Management Program
- 11.3 Attachment C Safety Software Quality Requirements
- 11.4 Attachment D Graded Approach
- 11.5 Attachment E Application of ASME NQA-1
- 11.6 Attachment F Integrated Management System
- 11.7 Attachment G Quality Assurance Implementation Plan

ATTACHMENT A – SUSPECT/COUNTERFEIT ITEMS PREVENTION

The following are **DOE O 414.1C**, **Attachment 3**, **Suspect/Counterfeit Items (S/CI) Prevention** requirements:

- (a) An S/CI prevention process must be developed and implemented as a part of the organization's quality assurance program and commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying and analyzing S/CIs, removing them, and preventing S/CIs from being supplied to DOE/NNSA and its contractors per DOE O 414.1C, Attachment 3.
- (b) Work processes must be developed and implemented using available S/CI information per DOE O 414.1C, Attachment 3.

GENERAL INFORMATION

Management Expectations:

• S/CI prevention processes will meet requirements consistent with guidance provided in DOE G 414.1-3, *Suspect/Counterfeit Items Guide*.

IMPLEMENTATION

DOE management delegates implementation authority for S/CI prevention through contracts and/or technical direction. DOE management monitors S/CI prevention practices through oversight activities.

Implementing Procedures and Documents:

- PL-226-01, EMCBC Oversight Plan
- IP-414-02, Assessment Procedure for Federal Employees

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

ATTACHMENT B – CORRECTIVE ACTION MANAGEMENT PROGRAM

The following are **DOE O 414.1C**, **Attachment 4**, **Corrective Action Management Program** requirements:

DOE line managers must perform corrective actions per DOE O 414.1C, Attachment 4, that effectively resolve safety, quality and other issues arising from –

- (a) findings identified during HQ Independent Oversight; Environment, Safety, and Health evaluations; Security or Cyber Security evaluations; and Emergency Management assessments (DOE O 470.2B, *Independent Oversight and Performance Assurance Program*);
- (b) judgments of need identified by Type A accident investigations (<u>DOE O 225.1A</u>, *Accident Investigations*);
- (c) findings identified by the Office of Aviation Management, Office of Management, Budget and Evaluation (<u>DOE O 440.2B</u>, *Aviation Management and Safety*); or
- (d) other sources as directed by the Secretary or Deputy Secretary, including crosscutting safety issues.

GENERAL INFORMATION

Management Expectations:

- Effectively implement the following requirements consistent with guidance provided in <u>DOE G 414.1-5</u>, *Corrective Action Program Guide*:
 - (a) Reporting Findings,
 - (b) Corrective Action Plan Development, Approval, and Review,
 - (c) Tracking and Reporting Implementation,
 - (d) Corrective Action Effectiveness Review.
 - (e) Lessons Learned.

IMPLEMENTATION

Implementing Procedures and Documents:

- PL-226-01, EMCBC Oversight Plan
- IP-414-02, Assessment Procedure for Federal Employees
- IP-414-03, EMCBC Issues/Action Management System
- IP-230-01, Operating Experience/Lessons Learned

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

ATTACHMENT C – SAFETY SOFTWARE QUALITY REQUIREMENTS

The following are **DOE** O **414.1C**, **Attachment 5**, **Safety Software Quality Assurance** (**SQA**) requirements:

- (a) Federal personnel with SQA responsibilities must have technical competency to carry out their duties. Technical qualification requirements will be specified in technical qualification standards. This process is coordinated with Federal Technical Capability Panel (FTCP) in accordance with the requirements of DOE M 426.1-1A, Federal Technical Capability Manual, and DOE-STD-1172-2003, Standard.
- (b) Work processes involving safety software must be developed and implemented using national or international consensus standards and must include the following elements.
 - (1) Facility design authority involvement in the identification of software requirements specification, acquisition, design, development, verification and validation (including inspection and testing), configuration management, maintenance, and retirement.
 - (2) Identify, document, and maintain safety software inventory.
 - (3) Establish grading levels for safety software. Document those grading levels in the OAP.
 - (4) Using the grading levels established and approved above, select and implement applicable SQA work activities from the following list to ensure that safety software performs its intended functions. ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2000, must be used to implement these work activities. The standards used must be specified by the user and approved by DOE. DOE G 414.1-4 provides acceptable implementation strategies and appropriate standards for these work activities.
 - Software project management and quality planning.
 - Software risk management.
 - Software configuration management.
 - Procurement and supplier management.
 - Software requirements identification and management.
 - Software design and implementation.
 - Software safety.
 - Verification and validation.
 - Problem reporting and corrective action.
 - Training of personnel in the design, development, use, and evaluation of safety software.

GENERAL INFORMATION

Management Expectations:

• Safety software quality assurance processes will meet requirements consistent with guidance provided in <u>DOE G 414.1-4</u>, *Safety Software Guide*.

IMPLEMENTATION

DOE management delegates implementation authority for safety software quality assurance through contracts and/or technical direction. DOE management monitors SQA practices through oversight activities.

Implementing Procedures and Documents:

- PL-226-01, EMCBC Oversight Plan
- IP-414-02, Assessment Procedure for Federal Employees

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

ATTACHMENT D - GRADED APPROACH

The following are **DOE O 414.1C Graded Approach** requirements:

Implement the DOE O 414.1C 10 QA criteria using a graded approach and describe how the criteria and graded approach are applied.

GENERAL INFORMATION

DOE O 414.1C defines the graded approach as:

Graded Approach: The process of ensuring that the levels of analysis, documentation, and actions used to comply with requirements is commensurate with –

- The relative importance to safety, safeguards, and security;
- The magnitude of any hazard involved;
- The life-cycle stage of a facility or item;
- The programmatic mission of a facility;
- The particular characteristics of a facility or item;
- The relative importance to radiological and non-radiological hazards; and
- Any other relevant factors.

The graded approach is used to determine the applicability of the QAP requirements to any activity and the extent of rigor in applying them. The graded approach is the application of controls commensurate with the complexity of the activity, the potential consequences of a failure, and the probability of failure. The level of control and verification appropriate for a task is dependent upon the consequences of the task not being performed properly. This is defined as applying quality assurance using a graded approach.

Management Expectations:

• The graded approach application will meet requirements consistent with guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*.

IMPLEMENTATION

Each DOE QA criterion is stated as an expectation for management of work, performance of work, and assessment of work. As such, rigorous quality assurance controls for any high risk activity at EMCBC and SLA projects might include: identifying required and/or appropriate standards, establishing a work plan to prescribe work, assigning responsibilities, specifying personnel qualification & training provisions, developing & implementing work control processes and procedures including configuration control, implementing procurement process control, instituting verification and validation of items or services performed or procured, and/or performing assessments to verify

adequacy of performance and to identify & implement improvement opportunities when performance is unsatisfactory.

Rigorous QA controls should be considered for activities that: (1) involve compliance with laws, regulations, agreements, or directives, (2) could result in failure to achieve enforceable milestones, (3) could have a significant adverse impact on the safety and health of the public, the workers or the environment, (4) could result in incorrect data or information being released externally, or (5) could result in significant financial loss because of failure to perform an activity correctly or in a timely manner.

Less rigorous or routine QA controls may be considered, when appropriate levels of analysis, documentation, and planned actions allow, for activities such as: (1) application of EMCBC policies procedures related to safety and regulatory issues, (2) providing program and acquisition direction, (3) review of contractor prepared documents such as those related to safety, regulatory, design, etc, (4) evaluation of contractor performance, (5) investigation of employee concerns, (6) interfacing where commitments or agreements are established with DOE-HQ or regulating agencies, (7) definition, preparation, and control of records, (8) review or conduct of evaluations or investigations of safety-related events, (9) implementation and evaluation of corrective actions, (10) obtaining safety and environmental related services or activities, and (11) conduct of management assessments. Minimal QA controls may be considered for activities such as the procurement of office supplies or internal correspondence that does not impact any of the above. This Attachment does not relax any of the requirements or management expectations contained in this QAP.

ATTACHMENT E – APPLICATION OF ASME NQA-1

The following are **DOE O 414.1C National or International Consensus Standards Applications** requirements:

DOE O 414.1C requires -

- (a) The use of national or international consensus standards where practicable and consistent with contractual or regulatory requirements (e.g., 10 CFR 830) and identify the standards used. Appropriate standards include the following:
 - ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications (for nuclear-related activities);
 - ANSI/ISO/ASQ Q 9001-2000, Quality Management System Requirements (for non-nuclear activities); and
 - ANSI/ASQ Z 1.13, *Quality Guidelines for Research*, 1999 (for non-nuclear research activities).
- (b) Apply additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory).

GENERAL INFORMATION

Management Expectations:

 Application of ASME NQA-1 will meet requirements consistent with guidance provided in <u>DOE G 414.1-2A</u>, <u>Quality Assurance Management System Guide</u>.

IMPLEMENTATION

A matrix is included showing the implementation relationship between the 18 ASME NQA-1 program requirements, the 10 DOE O 414.1C criteria, and the primary implementing procedures or documents:

APPLICATION OF ASME NQA-1 TO THE DEPARTMENT OF ENERGY ENVIRONMENTAL MANAGEMENT CONSOLIDATED BUSINESS CENTER (EMCBC) QUALITY ASSURANCE PROGRAM (QAP)

ASME NQA-1 REQUIREMENTS (See Note B)	/4	MANAGE	MENT OF	it count	TRAUTH A	County County	Little Strate St	DOE C		C CRIT	$\overline{}$		DOE EMCBC IMPLEMENTING DOCUMENTS
1. ORGANIZATION		•											PL-414-01, EMCBC Quality Assurance Program
QUALITY ASSURANCE PROGRAM		0	0	0	•	r					0	0	PL-414-01, EMCBC Quality Assurance Program
PROCUREMENT DOCUMENT CONTROL	1								0				IP-540-01, Procurement Authorities, Delegations, and Responsibilities
5. INSTRUCTIONS, PROCEDURES, & DRAWINGS							•						IP-250-01, Preparation, Review, Approval, Revision, and Distribution of EMCBC Implementing Procedures
6. DOCUMENT CONTROL					•								IP-250-01, Preparation, Review, Approval, Revision, and Distribution of EMCBC Implementing Procedures
7. CONTROL OF PURCHASED ITEMS & SERVICES									•				IP-540-01, Procurement Authorities, Delegations, and Responsibilities
15. CONTROL OF NONCONFORMING ITEMS				•					•				IP-540-01, Procurement Authorities, Delegations, and Responsibilities
16. CORRECTIVE ACTION				0									IP-414-02, Assessment Procedure for Federal Employees IP-414-03, Issue/Action Management System
17. QUALITY ASSURANCE RECORDS					0								EMCBC Records Management Policies, Plans and Procedures (PS-243-01 - IP-243-07)
18. AUDITS			0									•	IP-414-02, Assessment Procedure for Federal Employees IP-361-01, Training and Qualification for Federal Employees

NOTES:

- A. The 10 Criteria from DOE O 414.1C are listed by the three major categories: Management, Performance, and Assessment. Criteria 6 and 8 are not directly applicable to DOE EMCBC activities.
- B. ASME NQA-1 Requirements 3, 8, 9, 10, 11, 12, 13, and 14, are not directly applicable to DOE EMCBC/SLA activities. Where site-specific project applications vary from this base determination, a revised matrix is needed as part of the approved site QIP.

ATTACHMENT F – INTEGRATED MANAGEMENT SYSTEM

The following are **DOE O 414.1C Integrated Management System** requirements:

DOE O 414.1C requires -

The integration, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in DOE O 414.1C, the S/CI prevention process (Attachment 3), the Corrective Action Management Program (Attachment 4), and Safety Software Quality Requirements (Attachment 5) with other quality or management system requirements in DOE directives and external requirements, including as applicable:

- DOE P 450.4, *Safety Management System Policy*;
- DOE P 226.1A, Department of Energy Oversight Policy;
- NNSA, *Quality Management Policy*, QC-1 (quality management system for the nuclear weapons complex and weapons-related activities);
- DOE/RW-0333P DOE Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description; and
- DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Description*, (for the Waste Isolation Pilot Plant and related activities).

GENERAL INFORMATION

Management Expectations:

 Integration of this QAP with other quality or management system requirements will be consistent with guidance provided in <u>DOE G 414.1-2A</u>, <u>Quality Assurance</u> <u>Management System Guide</u>.

IMPLEMENTATION

The EMCBC assurance system for Quality Assurance, Integrated Safety Management, Integrated Safeguards and Security Management, Cyber Security, Emergency Management, and Business Operations is implemented through IP-414-03, EMCBC Issues/Action Management System. Where specific additional quality or management system requirements are needed, integration is implemented and documented per the requirements of this QAP in the applicable Quality Assurance Implementation Plan.

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

ATTACHMENT G – QUALITY ASSURANCE IMPLEMENTATION PLAN

INTRODUCTION

The EMCBC or SLA sites utilize the following primary processes to ensure work is being performed to established standards: operational awareness activities, assessments of facilities, operations, and programs, assessments of contractor assurance systems, evaluations of contractor performance, and self-assessments of DOE line management functions and performance.

In addition, the graded approach, standards application, configuration control, causal analysis and root cause analysis, QAP implementation, assessment, and oversight, verifications and validations, trending analysis, management reporting, corrective actions, improvement actions, and issues management, master assessment scheduling, independent assessment, annual quality program planning and reporting, and lessons learned are processes and tools utilized to assure quality is achieved.

The specific following functional areas are identified as being within the purview of the EMCBC Quality Assurance Program:

Integrated Safety Management which includes:

Environmental Protection, Safety & Health, Radiation Protection, Facility Safety, Packaging & Transportation Safety, Waste Management, Conduct of Operations, Conduct of Maintenance

Integrated Safeguards and Security Management which includes: Security Badging, Security Controls, Classified Documents Controls, Materials Controls

Cyber Security which includes:

Security Certification and Accreditation

Emergency Management which includes:

Emergency Planning, Preparation, and Actions, Continuity of Operations

Business Operations which includes:

Program and Project Management, Human Resources Management, Contracting/Procurement, Financial Management, Information Resources Management, Legal Services, Logistics Management, Property Management, Fleet Management, Energy Conservation, Records Management, Office of Legacy Management (LM) Transition, EEO/Diversity, Training/Development, and Technical Services

Implementing Procedures and Documents:

Oversight

- PL-226-01, EMCBC Oversight Plan
- IP-414-02, Assessment Procedure for Federal Employees

■ <u>IP-414-03, EMCBC Issues/Action Management System</u>

Quality Assurance

- PL-414-01, EMCBC Quality Assurance Program
- IP-250-01, Preparation, Review, Approval, Revision, and Distribution of EMCBC
 Implementing Procedures, Policy Statements, and Program Descriptions
- IP-414-02, Assessment Procedure for Federal Employees
- <u>IP-414-03, EMCBC Issues/Action Management System</u>
- EMCBC Records Management Policies, Plans and Procedures

Integrated Safety Management

- PL-442-01, EMCBC FEOSH Program
- PD-450-01, Environmental Management System
- IP-451-01, NEPA Compliance
- PL-451-02, EMCBC NEPA Public Participation Program Plan

Integrated Safeguards and Security Management

■ PL-470-02, EMCBC Security Plan

Cyber Security

■ PL-240-07, EMCBC Cyber Security Plan

Emergency Management

- IP-472-01, EMCBC Occupant Emergency Plan
- PL-471-01, EMCBC Continuity of Operations Plan

Business Operations

- EMCBC Business Management Planning Process and Procedures
- PL-250-02, EMCBC Directives Management Plan
- IP-540-01, Procurement Authorities, Delegations, and Responsibilities
- <u>IP-580-01</u>, Real Property
- IP-580-02, Personal Property

For SLA Sites – implementation documents are identified in the applicable SLA Site Quality Assurance Implementation Plan.

INSTRUCTIONS

If a SLA site chooses to utilize this QAP, then their supplemental Quality Assurance Implementation Plan will identify all applicable procedures and documents for

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implementation of their QA program. The QIP is developed utilizing the sample EMCBC QIP below as a template. The specific SLA site performs a gap analysis to determine the necessary procedures and documents for their site QA program needs. This is included within their QIP with reference to EMCBC procedures as needed.

SAMPLE - EMCBC QA IMPLEMENTATION PLAN

DOE O 414.1C Criteria	Processes	Procedures and Documents			
Management/Criterion 1—Program					
Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. Establish management processes, including planning, scheduling, and providing resources for work.	Planning Scheduling Resource Allocation Graded Approach NQA-1 Application	EMCBC Organization Chart EMCBC Strategic Plan Mission and Function Statement for the EMCBC EMCBC FRAM Definitions & Acronyms EMCBC Quality Assurance Program			
Management/Criterion 2—Personnel Training an	nd Qualification				
 Train and qualify personnel to be capable of performing assigned work. Provide continuing training to personnel to maintain job proficiency. 	Training Technical Qualification Professional Qualification	Training and Qualification for Federal Employees			
Management/Criterion 3—Quality Improvement					
1. Establish and implement processes to detect and prevent quality problems. 2. Identify, control, and correct items, services, and processes that do not meet established requirements. 3. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. 4. Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.	Oversight Facility Tours Walkthroughs Work Observation Document Reviews Meeting Attendance & Participation Ongoing Interaction w Contractor Workers, Support Staff, & Mgt Site Visits Facility Assessments Operations Assessments Program Assessments Contractor Assurance Systems Worker & Customer Feedback Causal & Root Cause Analysis Corrective Actions Improvement Actions Performance Evals Trending Analysis Verifications & Validations Self-Assessments	EMCBC Oversight Plan Assessment Procedure for Federal Employees EMCBC Issues/Action Management System Operating Experience/Lessons Learned			
Management/Criterion 4—Documents and Recor	eds				
1. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	Document Control Records Management	Preparation, Review, Approval, Revision, and Distribution of EMCBC Implementing Procedures Records Management Policy			

	DOE O 414.1C Criteria	Processes	Procedures and Documents
2.	Specify, prepare, review, approve, and maintain records.		Vital Records Identification and Protection Identifying, Filing & Maintaining Records File Plan Creation and Maintenance EMCBC Records Disaster, Prevention, Mitigation, and Recovery Plan Electronic Records Management Disposition of Records
Perfori	mance/Criterion 5—Work Processes		
1.	Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using	Quality Assurance Integrated Safety Mgt ISSM Cyber Security	Preparation, Review, Approval, Revision, and Distribution of EMCBC Implementing Procedures
2.	approved instructions, procedures, etc. Identify and control items to ensure their proper use.	Emergency Mgt Business Operations	
3.	Maintain items to prevent their damage, loss, or deterioration. Calibrate and maintain equipment used		
"	for process monitoring or data collection.		
Perform	mance/Criterion 6—Design		
1.	Design items and processes using sound engineering/scientific principles and appropriate standards.		
2.	Incorporate applicable requirements and design bases in design work and design changes.		
3.	Identify and control design interfaces.		
4.	Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.		
5.	Verify/validate work before approval and implementation of the design.		
Perfori	mance/Criterion 7—Procurement		
2.	Procure items and services that meet established requirements and perform as specified. Evaluate and select prospective suppliers	Acquisition Planning Vendor Surveys Bid Evaluations Contractor Oversight	Procurement Authorities, Delegations, and Responsibilities
3.	on the basis of specified criteria. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	Contract Admin Source Evaluation	
Perfor	mance/Criterion 8—Inspection and Accept	ance Testing	
1.	Inspect and test specified items, services, and processes using established acceptance and performance criteria.		
2.	Calibrate and maintain equipment used for inspections and tests.		
Assessi	nent/Criterion 9—Management Assessmer	nt	
	Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	Assessment	EMCBC Oversight Plan Assessment Procedure for Federal Employees
<u> </u>			

DOE O 414.1C Criteria	Processes	Procedures and Documents							
Assessment/Criterion 10—Independent Assessment									
Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement. Establish sufficient authority and freedom from line management for independent assessment teams.	Assessment	EMCBC Oversight Plan Assessment Procedure for Federal Employees							
3. Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed. Appendix A – Suspect/Counterfeit Items Prevention	ion								
Appendix B – Corrective Action Management Pr	 ogram								
	Reporting Findings Corrective Action Plan Tracking and Reporting Effectiveness Review Lessons Learned	EMCBC Oversight Plan Assessment Procedure for Federal Employees EMCBC Issues/Action Management System Operating Experience/Lessons Learned							
Appendix C – Safety Software Quality Requirement	ents								

Legend:
Blue – DOE and Contractor Implementation
Yellow – DOE Oversight and Contractor Implementation